

**SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS  
REPORTED IN D.D.N.J. NOS. 5621-5640**

*Adulteration*, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and its strength differed from, and its quality and purity fell below, the standard set forth in such compendium; and Section 501(c), the article was not subject to the provisions of Section 501(b); and its strength and quality differed from that which it purported or was represented to possess.

*Misbranding*, Section 502(a), the labeling of the article was false and misleading; Section 502(b)(2), the article was in package form, and it failed to bear a label containing an accurate statement of the quantity of contents; Section 502(e), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear (1) the common or usual name of the drug; and (2) the drug was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient, including the quantity, kind, or proportion of alcohol contained therein; Section 502(f)(1), the labeling of the article failed to bear adequate directions for use; Section 502(f)(2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions where its use may be dangerous to health, or against unsafe dosage or methods of duration of administration or application, in such manner and form, as are necessary for the protection of users.

*New-drug violation*, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

**NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION**

**5621. Clarimycin.** (F.D.C. No. 41634. S. No. 8-347 P.)

**QUANTITY:** 880 display cards, each containing 1 btl., at Pittsburgh, Pa.

**SHIPPED:** 12-9-57, from Jersey City, N.J., by Merritt Corp.

**LABEL IN PART:** (Btl.) "Contents: 5 Drams Clarimycin Anti-Biotic Acne Lotion \* \* \* Active Ingredients: Neomycin Sulphate, Allantoin."

**RESULTS OF INVESTIGATION:** The article was regarded as a new drug since it was represented to contain neomycin sulfate and was labeled with directions for use over an extended period of time.

**LIBELED:** 3-20-58, W. Dist. Pa.

**CHARGE:** 502(a)—the labeling of the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for acne, pimples, blackheads, and stubborn skin infections; and 505(a)—the article was a new drug which may not be introduced into interstate commerce, and an application filed pursuant to the law was not effective with respect to such drug.

**DISPOSITION:** 6-20-58. Default—destruction.

**5622. Pega Palo.** (F.D.C. No. 41618. S. No. 18-288 P.)

**QUANTITY:** 142 cellophane pkgs. at Salt Lake City, Utah.